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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,548	11/28/2000	Stephen R. Quake	3153/IG638US2	8333
7590 06/23/2005 DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/724,548		QUAKE ET AL.	
	Examiner		Art Unit	
	Brian J. Sines		1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1 – 9 & 16 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 – 21 of prior U.S. Patent No. 6,767,706 B2. This is a double patenting rejection.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57 – 59 & 67 – 69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 21 of U.S. Patent No. 6,767,706 B2. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because they are essentially directed to the same invention.

Regarding claims 57 & 67 – 69, the patent does not specifically claim the further incorporation of a plurality of loop channels within the microfluidic device. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of loop channels within the disclosed device.

Claims 10 – 15, 17 – 56 & 60 – 66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 21 of U.S. Pat. No. 6,767,706 B2 (hereinafter “Quake”) in view of U.S. Pat. No. 6,408,878 B2 (hereinafter “Unger”).

Regarding claims 10 – 15, 17 – 56 & 60 – 66, these claims recite various additional features, which are generally well known in the art of microfluidic apparatus in facilitating sample analysis and fluid transport. Unger teaches analytical microfluidic devices further comprising microfabricated elastomeric valve and pump systems. Hence, as evidenced by Unger, a person of ordinary skill in the art would have had a reasonable expectation for success in incorporating such features within an analytical microfluidic apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP §

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2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such features within an analytical microfluidic apparatus.

Regarding claims 10, 11, 15, 17, 29, 33, 39, 41 & 61, Unger teaches a microfluidic device comprising a detection region comprising a detection window (3620) and an associated detector (3644) (see col. 30, lines 13 – 22; figure 36). In addition, Unger teaches that the disclosed microfluidic device is used to process DNA molecules and peptides (see col. 39, lines 9 – 46).

Regarding claim 12, Unger teaches various pertinent flow channel depth and width dimensions (see col. 11, lines 4 – 56).

Regarding claims 13 & 31, Unger teaches the fabrication of microfluidic devices utilizing elastomeric materials and including microvalves formed from an elastomeric membrane material (see col. 7, line 45 – col. 9, line 58; col. 14, lines 1 – 67).

Regarding claims 14, 17, 18, 22, 28, 32, 35 & 40, Unger further teaches the incorporation of a transparent elastomeric material (see col. 3, lines 10 – 23)

Regarding claims 19, 20, 23, 31, 50 – 56 & 60, Unger teaches a microfluidic pumping system comprising a layered configuration and control lines in a monolithic integrated elastomeric structure (see col. 1, line 61 – col. 2, line 65).

Regarding claims 24, 25, 31 & 50, Unger teaches the formation and incorporation of microvalves (see col. 14, lines 1 – 51).

Regarding claims 26, 27, 36 & 38, Unger teaches the utilization of a pressurized fluid, such as air (see col. 19, lines 22 – 53). In addition, with respect to claims 37 & 38, Unger teaches that the disclosed microfluidic device is used to process biological fluids (see col. 38, lines 59 – 67).

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Regarding claim 30, the Courts have held that the change in form or shape, without any new or unexpected results, is an obvious engineering design. See *In re Dailey*, 149 USPQ 47 (CCPA 1976). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate circular loop channel.

Regarding claims 34, 40 & 62, Unger teaches the patterning of an array of oligonucleotides on a substrate (see col. 39, lines 35 – 42).

Regarding claims 42 – 46, these claims are considered intended use or process limitations.

Regarding claim 47, Unger teaches the use of a molded silicon elastomer (see col. 14, lines 35 – 51).

Regarding claim 48, Unger teaches the use of soft silicon lithography (see col. 12, lines 7 – 63).

Regarding claims 49 & 50, Unger teaches the incorporation of mixing channel structures (see col. 11, lines 34 – 46).

Regarding claim 60, Quake does not specifically claim the further incorporation of a plurality of loop channels within the microfluidic device. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of loop channels within the disclosed device.

Regarding claims 63 – 66, Unger teaches that the disclosed microfluidic apparatus incorporates the use of an array on a substrate (see col. 39, line 35 – 42). Microtiter plates comprising an array of wells are well known in the art for providing an arrayed

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configuration of sample materials. Therefore, it would have been obvious to a person to incorporate the use of a microtiter plate with an analytical microfluidic apparatus.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered, but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

